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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/558,948	GOLZI ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-21 and 27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-26 and 33-38* is/are rejected.

7)☒ Claim(s) *22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II (claims 15-38) in the reply filed 7/6/09 is acknowledged.

Applicant contends that PCT Rule 13.2 requires that the special technical features providing a technical relationship between the claimed inventions must be considered as a whole to determine the contribution that each of the claimed inventions makes over the prior art. Applicant argues that the examiner has not considered the contribution of the special technical features as a whole over the prior art but rather one limitation in isolation.

In response to applicant's arguments, the examiner notes that when a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In this case, Inventions I and II both have a common technical feature, which is a microcapsule having a core with a dimension ranging from 50-1200 um, a polymeric membrane, and an active ingredient. Since unity of invention has to be considered only in relation to the independent claims in an international application and not the dependent claims, this common technical feature is found in independent claims 1, which is drawn to Invention I and claims 15 and 22, which are drawn to Invention II.

Therefore, rather than one limitation in isolation, the examiner contends that the technical feature is present in all independent claims 1, 15, and 22. The examiner notes that because this technical feature as a whole is found in the prior art (see Thankur (US Publication No. 2002/0064563)), the feature cannot be construed as a "special technical feature" under PCT 13.2.

The examiner further acknowledges applicant's election of species b.), wherein the coating is water-insoluble and the active ingredient is water-soluble. Since there were no arguments present for this election of species requirement, it is assumed that this election was made without traverse.

Thus, the restriction/election of species is deemed proper and is made FINAL.

Claim Status

Claims 1-38 are pending. Claims 22-26 and 33-38 are drawn to the elected species. Claims 1-21 and 27-32 are withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 30, 2005 is in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered by the examiner. A signed copy of form 1449 is enclosed herewith.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 22 is objected to because of the following informalities. Claim 22 recites that the active principle is present in amounts ranging from 01% to 40%. The examiner notes that this amount should be 0.1% to 40%. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25 recites the limitation, “ethylcellulose and its derivates." Applicant has not described the claimed genus of "derivate" in a manner that would indicate they were in possession of the full scope of this genus, or even to describe what this genus is comprised of. Although the instant specification mentions the use of derivates, these derivates are not described, as well as the methods of preparation and isolation of these "derivates."

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, inter aria, "functional characteristics when coupled with a known or disclosed correlation

between function and structure..." Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claimed "derivates" encompass any ethylcellulose compound that contains the identical core as the instantly claimed compound, with a differing of substituents quoted for the identical purpose. Applicant has not described this genus in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use. As such, the claims lack adequate written description for the claimed "ethylcellulose and its derivates."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-26 and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 22 recites that the microcapsules contain "at least one water-soluble active ingredient homogeneously dispersed therein in the form of solid particles..." However, it is not clear from the claim whether the active ingredient is present in relation to the core and coating. The independent claim

fails to clarify whether the active ingredient is present in the core, coating, or the coating and core (i.e., throughout the entire microcapsule).

For purposes of examination, the examiner will interpret the active ingredient as being comprised in the core of the microcapsule.

Additionally, claim 24 recites the limitation, "…characterized by a modified release of the active ingredient." However, this limitation is unclear because the claim does not explicitly describe to what the release is modified from.

Claims 23, 25, 26 and 33-38 are rejected as being dependent on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 22-26, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thakur et al (US Publication No. 2002/0064563) as evidenced by "Topiramate," http://chemicalland21.com/lifescience/phar/TOPIRAMATE.htm, MSDS of "Cellulose acetate," and Skinner et al ("Evaluation of Hydroxypropylcellulose as a Direct Compression Binder," 2003, pp.1-10).

Thakur et al teach a pharmaceutical composition comprising core particles containing an active agent of topiramate at 18-21 wt.%, wherein the core particles have an initial particle size between about 100 um and 2500 um and are present in the composition in an amount of 85-93 wt.% (paragraphs 0015, 0018). The core particles are coated with a taste masking mixture ranging from about 7-15 wt.% of the total composition (paragraph 0013). According to Thakur et al, the core particles can comprise topiramate alone (i.e. granular or crystalline form) or topiramate and one or more excipients (paragraph 0022). As evidenced by "Topiramate," the active agent is water soluble (pg. 1). Thakur et al teach that the coating preferably comprises about 6-9 wt.% cellulose acetate and 2-5 wt.% povidone (paragraph 0018). As evidenced by MSDS, cellulose acetate is water-insoluble (pg. 3) and as evidenced by the instant specification, povidone or polyvinylpyrrolidone can be a water-soluble additive (pg. 10, line 1). Thakur et al further teach that ethylcellulose can also be used as a suitable taste masking agent as well as cellulose acetate (paragraph 0034).

However, instead of explicitly teaching microcapsules comprising a core having a diameter from 50-1200 um, Thakur et al teach microcapsules with a diameter range that overlaps and encompasses the claimed range. According to

MPEP 2144.05, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)*. Additionally, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the core sizes of the microcapsules. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal size of each microcapsule core in order to best achieve the desired results. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) &* MPEP 2144.05. Burden is on applicant to prove the criticality of the claimed range.

Regarding claim 22, the examiner notes that this claim is a product-by-process claim. As a result, a determination of patentability is only based on the product itself. Applicant is directed to MPEP 2113, which states that "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Regarding claims 36-37, Thakur et al teach that a preferred excipient used in the taste masking layer is povidone and more specifically PLASDONE K29/32 (see table 2, paragraphs 0032, 0033). Skinner et al provide evidence that PLASDONE K29/32, exhibits a volumetric mean diameter of 99 um and an

undersize value of 41 um (pg. 2). However, even though this membrane additive does not anticipate the claimed mean diameter of the additive in instant claims 36-37, it would have been obvious to an artisan of ordinary skill at the time the invention was made to reduce the size of these additives in the coating. One would have been motivated to do so during routine optimization to achieve desired flow properties, easy application of the coating, desired dissolution, and an appropriate binding effect.

Regarding claim 38, wherein the microcapsules are coated with a further coating layer, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add an additional layer to the microcapsules of Thakur et al. One would have been motivated to do so in order to further control the release of topiramate from the pharmaceutical composition. The examiner notes that manipulating factors to control the release the drug is obvious because a skilled artisan would be motivated to do so depending on the needs of a particular patient population.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thakur et al (US Publication No. 2002/0064563) as evidenced by "Topiramate," http://chemicalland21.com/lifescience/phar/TOPIRAMATE.htm, MSDS of "Cellulose acetate," and Skinner et al ("Evaluation of Hydroxypropylcellulose as a Direct Compression Binder," 2003, pp.1-10) in view of Banakar ("Pharmaceutical Dissolution Testing," Volume 49, 1992, pg. 144).

The disclosure of Thakur et al is discussed above. To reiterate from above, topiramate can be present by itself in the core, wherein the core particles can have a particle size between about 100-2500 um.

However, Thakur et al do not teach that the active ingredient has dimensions from 0.1-80 um or more specifically from 1-30 um.

Banakar teaches that reduction in particle size of drugs contained in tablets or capsules will enhance dissolution and absorption, which can be attributed to tablet production.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to reduce the particle size of the active ingredients contained within the pharmaceutical compositions of Thakur et al. One would have been motivated to do so depending on the desired dissolution rate and bioavailability of the drug. More specifically, one would have been motivated to reduce the particle size of the active ingredients of Thakur et al in order to achieve a higher dissolution rate and enhanced absorption.

Claims 22-25, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell (US Patent No. 5,252,337) as evidenced by Santa Cruz Biotechnology, http://www.scbt.com/datasheet-200199.html.

Powell teaches an ethylcellulose microencapsulated formulation of a calcium channel blocker with a controlled release from about 8 to about 24 hours (column 3, lines 3-6). Such calcium channel blockers include diltiazem, nifedipine, or verapamil (column 3, lines 40-42). As evidenced by Santa Cruz

Biotechnology, diltiazem is soluble in water. According to Powell, the core may be any pharmaceutically acceptable, non-functional solid carrier or it may be a crystal of the calcium channel blocker itself (column 3, lines 47-51). The loaded pellets or granules (core) comprise 40-50 wt.% of calcium channel blocker, 40-50 wt.% of the core, and from about 2-3 wt.% of binder (column 3, lines 61-65). The size of the loaded calcium channel blocker pellets of the invention are from 289-1410 um (column 4, lines 9-12). Powell further teaches that the pellets are coated with 2-10 wt.% of ethylcellulose (column 4, lines 30-32).

However, instead of explicitly teaching microcapsules comprising a core having a diameter from 50-1200 um, Powell teaches microcapsules with a diameter range that overlaps and encompasses the claimed range. According to MPEP 2144.05, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)*. Additionally, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the core sizes of the microcapsules. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal size of each microcapsule core in order to best achieve the desired results. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* & MPEP 2144.05. Burden is on applicant to prove the criticality of the claimed range.

Regarding claim 22, the examiner notes that this claim is a product-by-process claim. As a result, a determination of patentability is only based on the product itself. Applicant is directed to MPEP 2113, which states that "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Regarding claim 38, wherein the microcapsules are coated with a further coating layer, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add an additional layer to the microcapsules of Powell. One would have been motivated to do so in order to further control the release of the calcium channel blocker from the pharmaceutical composition. The examiner notes that manipulating factors to control the release the drug is obvious because a skilled artisan would be motivated to do so depending on the needs of a particular patient population.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell (US Patent No. 5,252,337) as evidenced by Santa Cruz Biotechnology, http://www.scbt.com/datasheet-200199.html in view of Banakar ("Pharmaceutical Dissolution Testing," Volume 49, 1992, pg. 144).

The disclosure of Powell is discussed above. To reiterate from above, the calcium channel blocker can be present by itself in the core, wherein the core can have a particle size between about 289-1410 um.

However, Powell does not teach that the active ingredient has dimensions from 0.1-80 um or more specifically from 1-30 um.

Banakar teaches that reduction in particle size of drugs contained in tablets or capsules will enhance dissolution and absorption, which can be attributed to tablet production.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to reduce the particle size of the active ingredients contained within the pharmaceutical compositions of Powelll. One would have been motivated to do so depending on the desired dissolution rate and bioavailability of the drug. More specifically, one would have been motivated to reduce the particle size of the active ingredients of Powell in order to achieve a higher dissolution rate and enhanced absorption.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25, 35, and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 19-22, and 24-28 of copending Application No. 10/521,598. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the copending application are drawn to microcapsules comprising drug microparticles with a first layer disposed over said microparticles consisting essentially of ethylcellulose, and a second layer disposed over said first layer comprising an acrylic polymer. The microcapsules have a drug to ethylcellulose weight ratio of from 1:1 to 30:1 and a median diameter of 100-400 um. The drug can be selected from antibiotics, antivirals, analgesics, etc.

The difference between the copending claims and the instant claims is that there is no particular weight percentage of active ingredient and amount of coating specified in the copending claims.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amount of active ingredient and coating depending on the desired release characteristics. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. See

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05. Burden is on applicant to prove the criticality of the claimed range.

This is a provisional obviousness-type double patenting rejection.

Claims 22-26, 35, and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 11-12, 13, and 18 of US Patent No. 5,296,236 as evidenced by PPC, "Ketorolac tromethamine". Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the patent are drawn to microgranules comprising a drug and at least 3 coatings including a first coating including derivatives of cellulose. According to the specification of '236, derivatives of cellulose can include ethylcellulose (column 5, lines 6-7). The drug can be ketorolac tromethamine, which as evidenced by PPC, is a water-soluble drug. The microgranules have dimensions of 125-300 um.

The difference between the patented claims and the instant claims is that there is no particular weight percentage of active ingredient and amount of coating specified in the patented claims.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amount of active ingredient and coating depending on the desired release characteristics. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. See

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05. Burden is on applicant to prove the criticality of the claimed range.

Claims 22-25, 35, and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of US Patent No. 5,510,119. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the patent are drawn to microgranules comprising a drug and at least 3 coatings including a polymeric hydrophobic coating. According to the specification of '119, the coating can include ethylcellulose as a polymer (column 5, line 3). The microgranules have dimensions of 50-600 um.

The difference between the patented claims and the instant claims is that there is no particular weight percentage of active ingredient and amount of coating specified in the patented claims.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amount of active ingredient and coating depending on the desired release characteristics. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* & MPEP 2144.05. Burden is on applicant to prove the criticality of the claimed range.

Conclusion

Claims 22-26 and 33-38 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW
/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
October 13, 2009